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| APPLICATION NO.  | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|--|-------------|----------------------|---------------------|------------------|
| 09/518,076   | 03/03/2000  | Leland Shapiro       | 114232.109          | 5437             |
| 27160  | 7590        | 10/18/2005           | EXAMINER            |                  |
| KATTEN MUCHIN ROSENMAN LLP<br>525 WEST MONROE STREET<br>CHICAGO, IL 60661-3693 |             |                      | HILL, MYRON G       |                  |
|  |             |                      | ART UNIT            | PAPER NUMBER     |
|  |             |                      | 1648                |                  |
| DATE MAILED: 10/18/2005  |             |                      |                     |                  |

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/518,076

Applicant(s)

SHAPIRO, LELAND

Examiner

Myron G. Hill

Art Unit

1648

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 27 July 2005.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-39 is/are pending in the application.
- 4a) Of the above claim(s) 9-11 and 16-39 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-8 and 12-15 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

## **DETAILED ACTION**

### ***Continued Examination Under 37 CFR 1.114***

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submissions filed on 13 April 2005 and 27 July 2005 have been entered.

### ***Election/Restrictions***

Applicant's election of (Benzyloxycarbonyl)-L-valyl-N-[1-(2-[5-(3-methylbenzyl)-1,3,4-oxydioxolyl]carbonyl)-2-(S)-methylpropyl]-L-prolinamide is acknowledged.

Applicant's election in the reply following RCE is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Claims 1-8, and 12-15 are under consideration.

### ***Claim Objections***

Claims 9-11 and 16-39 are objected to because of the following informalities:

The text of all pending claims must be written out. Appropriate correction is required.

### ***Rejections***

#### ***Claim Rejections - 35 USC § 103***

Claims 1- 8, 12- 14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lezdey (US 5,532,215, previously cited) and Guittard *et al.* (US 5358721).

Lezdey teaches a method to treat a subject suffering from a herpes virus infection, eczema or related conditions with an AAT compound by topical or systemic dosing at about 1mg/kg body weight (column 5, lines 16- 33, column 6, line 32 – column 7, Example 1, column 12, lines 10- 12, Claims 1 and 2). Lezdey teaches that AAT is a serine proteinase inhibitors that is in the subgroup called serpins (column 3, lines 39- 41) and that alpha 1- protease inhibitor (alpha 1- PI) is another name for AAT (column 5, line 19).

Guittard *et al.* teach that vidarabine, azidothymidine, and ganciclovir are antiviral agents (claim 10) and known to have anti-Herpes activity and are useful in treating herpes related conditions (claim 13 defines what the antiviral agents are against).

One of ordinary skill in the art at the time of invention would have combined the treatments of Lezdey and Guittard *et al.* with the expectation of at least additive effect of the two treatments.

Thus, it would be *prima facie* obvious to combine the treatments of Lezdey and Guittard *et al.* with the expectation of success of at least additive effect of the two treatments.

Claims 1, 3, 4, and 15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lezdey (US 5,532,215, previously cited) in view of Gyorkos *et al.* (US 5,618,852, previously cited) and Guittard *et al.* (US 5,358,721).

Lezdey teaches a method to treat a subject suffering from a herpes virus infection, eczema or related conditions with an AAT compound by topical or systemic dosing at about 1mg/kg body weight (column 5, lines 16- 33, column 6, line 32 – column 7, Example 1, column 12, lines 10- 12, Claims 1 and 2). Lezdey teaches that AAT is a serine proteinase inhibitors that is in the subgroup called serpins (column 3, lines 39- 41) and that alpha 1- protease inhibitor (alpha 1- PI) is another name for AAT (column 5, line 19).

Lezdey does not teach related compounds that have AAT-like activity.

Gyorkos teaches a series of compounds including (Benzyloxycarbonyl)-L-valyl-N-[1-(2-[5-(3-methylbenzyl)-1,3,4-oxadiazolyl]carbonyl)-2-(S)-methylpropyl]-L-prolinamide (Example 1) that are serine proteinase inhibitors that are low molecular weight, high stability, stability in physiological conditions, is a serpin, and can be formulated as a pharmaceutical (column 11, line 60- column 12, line 9, column 13, line 34- column 14, line 47, and Example I). Gyorkos also teaches that these compounds are inhibitors of alpha-1 protease (column 1, lines 8- 53).

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Guittard *et al.* teach that vidarabine, azidothymidine, and ganciclovir are antiviral agents (claim 10) and known to have anti-Herpes activity and are useful in treating herpes related conditions (claim 13 defines what the antiviral agents are against).

One of ordinary skill in the art at the time of the invention would have known that the compounds described by Gyorkos had the activity exhibited by mammalian alpha-1-antitrypsin that are required to meet the requirements of the method of Lezdey. One of ordinary skill in the art at the time of the invention would have known the benefits of the compounds taught by Gyorkos as discussed above and would have used them in the method of Lezdey.

One of ordinary skill in the art at the time of invention would have combined the treatments of Lezdey in view of Gyorkos and Gosselin *et al.* with the expectation of at least additive effect of the two treatments.

Thus, it would have been *prima facie* obvious to use the compounds of Gyorkos including (Benzyloxycarbonyl)-L-valyl-N-[1-(2-[5-(3-methylbenzyl)-1,3,4-oxoxydiacyl]carbonyl)-2-(S)-methylpropyl]-L-prolinamide knowing that it has AAT activity in the method of Lezdey with the expectation of success in a combination therapy.

### **Conclusion**


No claim is allowed.


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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Myron G. Hill whose telephone number is 571-272-0901. The examiner can normally be reached on 8:30 am-5 pm Mon-Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on 571-272-0902. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

  
Myron G. Hill  
Patent Examiner  
14 October 2005

  
JAMES HOUSEL 10/17/05  
SUPERVISORY PATENT EXAMINER  
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